THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE HONORABLE BOARD OF PATENT APPEALS AND INTERFERENCES

In re the Application of:

Robert C. STEVENS

Application No.: 10/075,053 Examiner: Bhisma Mehta

Filed: February 13, 2002 Docket No.: RSTZ 2 00011-3

For: REINFORCED CATHETER DEVICE, CATHETER STOCK, AND METHODS AND APPARATUS FOR MAKING SAME

BRIEF ON APPEAL

Appeal from Group/Art Unit 6767

Michael E. Hudzinski, Esq., Reg. No. 34,185
Rankin, Hill, Porter & Clark LLP
38210 Glenn Avenue
Willoughby, Ohio 44094-7808
Telephone: (216) 566-9700
Attorneys for Appellants

I. REAL PARTY IN INTEREST

The real party in interest is AngioDynamics, Inc., 603 Queensbury Avenue, Queensbury, New York, 12840, by way of an Assignment recorded in the U.S. Patent and Trademark Office on February 15, 2006 at Reel 017164, Frame 0908.

II. RELATED APPEALS AND INTERFERENCES

There are no prior or pending appeals, interferences or judicial proceedings, known to appellants, appellants' representative, or assignee, that may be related to, or which will directly affect or be directly affected by or have a bearing upon the Board's decision in the pending Appeal.

III. STATUS OF CLAIMS

Claims 1, 3-11, 24, 26-28, 41, 43-61, and 63-65 are on appeal.

Claims 1, 3-24, 26-41, 43-61, and 63-65 are pending in the application, of which claims 12-23 and 29-40 are withdrawn from consideration.

None of the claims have been allowed.

None of the claims were objected to only for being dependent from a rejected base claim, but are otherwise allowable.

Claims 1, 3-11, 24, 26-28, 41, 43-61, and 63-65 are rejected.

IV. STATUS OF AMENDMENTS

No Amendment After Final Rejection has been filed which would have proposed amendments to the claims.

A non-final Office Action was mailed from the U.S. Patent and Trademark Office in this application on January 19, 2007. Appellant tendered an amendment to that Office Action on April 19, 2007 wherein only claim 41 was amended. Substantive arguments were presented to the Examiner in that amendment, however.

Thereafter, a further Office Action was issued by the U.S. Patent and Trademark Office on July 2, 2007. That Action was made final.

No amendments were tendered by appellant in response to the final Office Action. Rather, appellant prepared and filed a Notice of Appeal on July 20, 2007.

V. SUMMARY OF CLAIMED SUBJECT MATTER

In accordance with one embodiment such as set out in independent claim 1, a reinforced catheter (68) comprises a continuous coil reinforcement member 54 (FIG. 2C) carried on an elongate flexible tubular member (50), a first flexible coating covering (58) the coil reinforcement member, and a second flexible outer coating (62) carrying a first portion (74) of the first outer coating. The elongate flexible tubular member defines a lumen of the catheter (p4, ln. 22), and has a first end defining a proximal end (69) of the catheter and a second end defining a distal end (67) of the catheter. The continuous coil reinforcement member (54) is carried on the elongate flexible tubular member and extends from the proximal end (69) of the catheter and terminates at the second end (67) of the tubular member (p4, ln. 25 – p4, ln.28). The first flexible outer coating (58) covers the coil reinforcement member (54) and the tubular member (50) substantially entirely between the proximal end (69) of the catheter and the distal end (67) of the catheter. The second flexible outer coating (62) covers a first portion (74) of the first outer coating (58) between a first transition area (73) of the catheter and the proximal end (69) of the catheter. A second portion (72) of the first outer coating (68) between the first transition area (73) and the distal end (67) of the catheter is uncovered by the second outer coating and defines a flexible distal tip (72) of said catheter. The first coating (58) is softer than the second coating (62)(p13, ln. 16 – p16, ln. 30)(p. 14, l. 8).

In further accordance therewith, such as set out in dependent claim 3, the first flexible outer coating has a Shore hardness of about 40D (p. 14, l. 7), and the second flexible outer coating has a Shore hardness of about 70D (p. 14, l. 8).

In further accordance therewith, such as set out in dependent claim 4, the reinforced catheter further includes a marker band (82, FIG. 4d) disposed adjacent the distal end of the catheter on the first flexible outer coating (p. 16, l. 1-13).

In further accordance therewith, such as set out in dependent claim 5, the marker band is formed of a one of gold material and platinum material (p. 18, l. 4-6).

In further accordance therewith, such as set out in dependent claim 6, the elongate flexible tubular member is formed of a polytetrafluoroethylene (PTFE) material (p. 9, l. 10).

In further accordance therewith, such as set out in dependent claim 7, the continuous coil reinforcement member is a stainless steel wire (p. 10, l. 9).

In further accordance therewith, such as set out in dependent claim 8, the continuous coil reinforcement member defines a helical pattern (p. 10, l. 18) (FIGS. 2c-2f).

In further accordance therewith, such as set out in dependent claim 9, a thickness of the distal end of the catheter is less than a thickness of the proximal end of the catheter (FIGS. 4b-4d) (p. 15, l. 1-9).

In further accordance therewith, such as set out in dependent claim 10, the first outer coating is comprised of one of a group of materials consisting of nylon material and urethane material (p. 15, l. 21-30).

In further accordance therewith, such as set out in dependent claim 11, the second outer coating is comprised of a nylon material (p. 13, l. 16-22).

In accordance with another embodiment such as set out in independent claim 24, a reinforced catheter stock (p5, ln.25 – p 6, ln. 1) for manufacturing reinforced catheters comprise a selected length of an elongate flexible tubular member (50), a continuous coil reinforcement member (54) (FIG. 2c), a continuous outer coating of a first material (58)(Fig. 2e), and a continuous outer coating of a second material (62)(Fig. 2f). The selected length of the elongate flexible tubular member (50) defines a lumen (p4, ln. 22) of the catheter stock and has a first end defining a lead end of the catheter stock and a second end defining a trailing end of the catheter stock. The continuous coil reinforcement member (54) is carried on the elongate flexible tubular member (50) and extends from the lead end of the catheter stock to the trailing end of the catheter stock entirely (p4, ln. 25 – p4, ln.28). The continuous outer coating of the first material covers the coil reinforcement member and the tubular member substantially entirely between the lead end of the catheter stock and the trailing end of the catheter stock (FIG. 4a). The continuous outer coating of the second material covers the continuous outer coating of the first material substantially entirely between the lead end of the catheter stock and the trailing end of the catheter stock (FIG. 4b). The first material is softer than the second material (p13, ln. 16 – p16, ln. 30)(p. 14, l. 8).

In further accordance therewith, such as set out in dependent claim 26, the continuous coil reinforcement member defines a helical pattern (p. 10, l. 18) (FIGS. 2c-2f), the first material has a Shore hardness of about 40D (p. 14, l. 7), and the second material has a Shore hardness of about 70D (p. 14, l. 8).

In further accordance therewith, such as set out in dependent claim 27, the elongate flexible tubular member is a polytetrafluoroethylene (PTFE) material (p. 9, l. 10).

In further accordance therewith, such as set out in dependent claim 28, the continuous coil reinforcement member is a stainless steel wire (p. 10, l. 9).

In accordance with another embodiment such as set out in independent claim 41, a reinforced catheter comprises an elongate flexible tubular member (50), a first flexible outer coating (58), a second flexible outer coating (62), and a coil reinforcement member (54). The elongate flexible tubular member defines a lumen (p4, ln. 22) of the catheter and has a first end (69)(Figs. 4b-4d) defining a proximal end of the catheter and a second end (67)(Figs. 4b-4d) defining a distal end of the catheter. The first flexible outer coating (58) covers the tubular member fully between the proximal end of the catheter to the distal end of the catheter (p4, ln. 25 – p4, ln.28). The second flexible outer coating (62)covers a first portion of the first outer coating at the proximal end of the catheter. The second portion of the first outer coating is uncovered by the second outer coating at the distal end of the catheter and defines a flexible distal tip (72)(Figs. 4b-4d)) of the catheter. The first coating (58) is softer than the second coating (62)(p13, ln. 16 – p16, ln. 30)(p. 14, l. 8). The coil reinforcement member (54) is carried on the elongate flexible tubular member (50) and extends from the first end of the tubular member and terminates at the second end of the tubular member.

In further accordance therewith, such as set out in dependent claim 43, the first flexible outer coating has a Shore hardness of about 40D (p. 14, l. 7), and the second flexible outer coating has a Shore hardness of about 70D (p. 14, l. 8).

In further accordance therewith, such as set out in dependent claim 44, the reinforced catheter further comprises a marker band (82, Fig. 4d) disposed adjacent the distal end of the catheter on the first flexible outer coating (p. 16, l. 1-13).

In further accordance therewith, such as set out in dependent claim 45, the marker band is formed of a one of gold material and platinum material (p. 18, l. 4-6).

In further accordance therewith, such as set out in dependent claim 46, the elongate flexible tubular member is formed of a polytetrafluoroethylene (PTFE) material (p. 9, l. 10).

In further accordance therewith, such as set out in dependent claim 47, the coil reinforcement member is a stainless steel wire (p. 10, l. 9).

In further accordance therewith, such as set out in dependent claim 48, the coil reinforcement member defines a helical pattern (p. 10, l. 18) (FIG. 2c-2f).

In further accordance therewith, such as set out in dependent claim 49, a thickness of the distal end of the catheter is less than a thickness of the proximal end of the catheter (FIGS. 4b-4d) (p. 15, l. 1-9).

In further accordance therewith, such as set out in dependent claim 50, the first outer coating is comprised of one of a group of materials consisting of nylon material and urethane material (p. 15, l. 21-30).

In further accordance therewith, such as set out in dependent claim 51, the second outer coating is comprised of a nylon material (p. 13, l. 16-22).

In accordance with yet another embodiment such as set out in independent claim 52, a reinforced catheter comprises an elongate flexible tubular member (50), a continuous coil reinforcement member (54), and first (58) and second (62) flexible outer coatings. The elongate flexible tubular member has first () and second ends and defines a lumen (p4, ln. 22) of the catheter. The continuous coil reinforcement member is disposed on the elongate flexible tubular member and terminates at the first and second ends of the tubular member. A first flexible outer coating (58) covers the coil reinforcement member (54) and the tubular member (50) substantially entirely between the first end (69) and the second end (67) of the tubular member (p4, ln. 25 – p4, ln.28). The second flexible outer coating (62) covers a first portion (74) of the first outer coating from a first transition area (73) of the catheter and terminates at the first end (69) of tubular member. A second portion of the first outer coating (58) is uncovered by the second outer coating and defines a flexible distal tip (72) of the catheter from the first transition area (73) and terminates at the second end

(67)of the tubular member (p14, ln. 22 – p14, ln. 32). The first coating is softer than the second coating (p13, ln. 16 – p16, ln. 30)(p. 14, l. 8).

In further accordance therewith, such as set out in dependent claim 53, the first flexible outer coating has a Shore hardness of about 40D (p. 14, l. 7), and the second flexible outer coating has a Shore hardness of about 70D (p. 14, l. 8).

In further accordance therewith, such as set out in dependent claim 54, the reinforced catheter further comprises a marker band (82) (FIG. 4d) disposed adjacent the second end of the tubular member on the first flexible outer coating (p. 16, l. 1-13).

In further accordance therewith, such as set out in dependent claim 55, the marker band is formed of a one of gold material and platinum material (p. 18, l. 4-6).

In further accordance therewith, such as set out in dependent claim 56, the elongate flexible tubular member is formed of a polytetrafluoroethylene (PTFE) material (p. 9, l. 10).

In further accordance therewith, such as set out in dependent claim 57, the continuous coil reinforcement member is a stainless steel wire (p. 10, l. 9).

In further accordance therewith, such as set out in dependent claim 58, the continuous coil reinforcement member defines a helical pattern (p. 10, l. 18) (FIGS. 2c-2f).

In further accordance therewith, such as set out in dependent claim 59, the first outer coating is comprised of one of a group of materials consisting of nylon material and urethane material (p. 15, l. 21-30).

In further accordance therewith, such as set out in dependent claim 60, the second outer coating is comprised of a nylon material (p. 13, l. 16-22).

In accordance with yet another embodiment such as set out in independent claim 61, a reinforced catheter comprises an elongate flexible tubular member (50), first (58) and second (62) flexible outer coatings, and a coil reinforcement member (54). The elongate flexible tubular member defines a lumen (p4, ln. 22) of the catheter and has a first end (69) defining a proximal end of the catheter and a second end (67) defining a distal end of the catheter. The first flexible outer coating (58) covers the tubular member completely from the distal end (67) of the catheter to the proximal

end (69) of the catheter. The second flexible outer coating (62) covers a first portion of the first outer coating at the proximal end (74) of the catheter. A second portion of the first outer coating at the distal end (72) of the catheter is uncovered by the second outer coating and defines a flexible distal tip (72) of the catheter (p14, ln. 22 – p14, ln. 32). The first coating is softer than the second coating (p13, ln. 16 – p16, ln. 30)(p. 14, l. 8). The coil reinforcement member (54) is carried on the elongate flexible tubular member (50) and extends in the distal tip of the catheter completely to the second end (p4, ln. 25 – p4, ln. 28).

In further accordance therewith, such as set out in dependent claim 63, the coil reinforcement member terminates at said first end of said tubular member (p. 4, l. 25-28) (p. 5, l. 2-24).

In further accordance therewith, such as set out in dependent claim 64, the first flexible outer coating has a Shore hardness of about 40D (p. 14, l. 7), the second flexible outer coating has a Shore hardness of about 70D (p. 14, l. 8).

In accordance with yet a still further embodiment such as set out in independent claim 65, a reinforced catheter comprises an elongate flexible tubular member (50), a continuous coil reinforcement member (54), and first (58) and second (62) outer coatings. The elongate flexible tubular member (50) has first and second ends and defines a lumen (p4, ln. 22) of the catheter. The continuous coil reinforcement member is disposed on the elongate flexible tubular member and extends completely to and terminates at the second end of the tubular member (p4, ln. 25 – p4, ln. 28). The first flexible outer coating covers the coil reinforcement member and the tubular member substantially entirely between the first end (69) and the second end (67) of the tubular member. The second flexible outer coating (62) covers a first portion of the first outer coating (58) from a first transition area (73) of the catheter and terminates at the first end (69) of the tubular member. A second portion of the first outer coating (58) is uncovered by the second outer coating (62) and defines a flexible distal tip (72) of the catheter from the first transition area (73) and terminates at the second end (67) of the tubular member (p14, ln. 22 – p14, ln. 32). The first coating is softer than the second coating (p13, ln. 16 – p16, ln. 30)(p. 14, l. 8).

VI GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The following grounds of rejection are presented for review:

Claims 1, 3, 6-11, 24, 26-28, 41, 43, 46-53, 56-61, and 63-65 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,951,539 to Nita, et al. (hereinafter "Nita");

Claims 1, 3, 6-11, 24, 26-28, 41, 43, 46-53, 56-61, and 63-65 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Nita in view of U.S. Patent Application Publication No. 2003/0109851 to Landuyt (hereinafter "Landuyt");

Claims 4, 5, 44, 45, 54, and 55 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Nita as applied to claims 1, 41, and 52, and further in view of U.S. Patent No. 5,728,065 to Follmer, et al. (hereinafter "Follmer"); and,

Claims 4, 5, 44, 45, 54, and 55 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Nita in view of Landuyt as applied to claims 1, 41, and 52, and further in view of Follmer.

The issues presented on Appeal are as follows:

1. Whether claims 1, 3, 6-11, 24, 26-28, 41, 43, 46-53, 56-61, and 63-65 are unpatentable under 35 U.S.C. § 103(a) over Nita;

2. Whether claims 1, 3, 6-11, 24, 26-28, 41, 43, 46-53, 56-61, and 63-65 are unpatentable under 35 U.S.C. § 103(a) over Nita in view of Landuyt;

3. Whether claims 4, 5, 44, 45, 54, and 55 are unpatentable under 35 U.S.C. § 103(a) over Nita in view of Follmer; and,

4. Whether claims 4, 5, 44, 45, 54, and 55 are unpatentable under 35 U.S.C. § 103(a) over Nita in view of Landuyt as applied to claims 1, 41, and 54, and further in view of Follmer.

VII. ARGUMENT

A. Prosecution Background

This is the second Brief on Appeal filed by appellant in this matter. The first Brief was filed on August 5, 2005. At that time, the issues presented were whether U.S. Patent No. 5,972,143 to Stevens (hereinafter "Stevens") anticipated claims 1, 2, 6-11, 24, 25, 17, and 28 and, whether Stevens renders claims 3 and 26 obvious. Further, the issues presented in that first Brief on Appeal were whether Stevens in view of U.S. Patent No. 5,147,315 to Weber (hereinafter "Weber") renders claim 4 obvious, and whether Stevens in view of Weber and further in view of U.S. Patent No. 5,843,051 to Adams, et al. (hereinafter "Adams") renders claim 5 obvious.

Although the claims remain substantially unchanged, none of the Stevens, Weber, or Adams patents are being applied against the pending claims at present. Accordingly, it is believed that the Office has conceded that the claims are allowable over those prior references as the rejections thereof have now been withdrawn by the Office.

In response to the Brief on Appeal filed on August 5, 2005, the Examiner responded with a further Office Action mailed on October 19, 2005. That Action was made "non-final" and rejected claims 1, 3-11, 24, 26-28, and 41-51. The Examiner conceded that the "application has been made non-final because claims 41-51 had not been examined and inconsistencies between rejected, canceled, and withdrawn claims. (sic) therefore, this application was not in condition for appeal." (emphasis in original). Claims 1, and 6-11 were rejected as being anticipated by Stevens. Claims 3 and 26 were rejected as being unpatentable over Stevens. Claim 4 was rejected as being unpatentable over Stevens in view of Weber. Claim 5 was rejected as being unpatentable over Stevens in view of Weber and further in view of Adams. The Examiner entertained a discussion of claims 24, 27, 28, 41, 42, and 43 relative to Stevens at the bottom of page 4 of that Office Action but without a specific rejection of those claims over Stevens. Claims 44-51 were rejected as being unpatentable over Stevens in view of U.S. Patent No. 5,972,143 to Murphy-Chutorian (hereinafter "Murphy").

Appellant filed an Amendment B on January 18, 2006 which received a further Communication from the Office mailed on April 11, 2006 wherein the Examiner took the position that the amendment was not fully responsive to the prior Office Action because the reply did not present arguments pointing out the specific distinctions believed to render the newly added claims patentable over any applied references.

Appellant responded to that Communication on May 10, 2006.

A further Office Action issued on August 2, 2006 from a second Examiner. In that Action, claims 47 and 48 were rejected because of an informality and claims 4, 5, 44, 45, 54, and 55 were rejected as being indefinite. The Examiner applied U.S. Patent No. 5,951,539 to Nita, et al. (hereinafter "Nita") as an anticipatory reference under 35 U.S.C. 102(b) against claims 1, 3, 6-11, 24, 26-28, 41-43, 46-53, and 56-65. Claims 4, 5, 44, 45, 54, and 55 were rejected under 35 USC 103(a) as being unpatentable over Nita in view of U.S. Patent No. 5,728,065 to Follmer, et al. (hereinafter "Follmer").

Appellant filed an Amendment C on November 2, 2007 in response to the Office Action of August 2, 2007. In that amendment, appellant amended independent claim 1 to clarify the claim to recite that the continuous coil reinforcement member is carried on the tubular member and extends from the proximal end of the catheter and terminates at the second end of the tubular member. The second end of the tubular member defines the distal end of the elongate flexible member portion of the catheter recited in the claim. Also, independent claim 24 was amended to clarify that the continuous coil reinforcement member extends from the lead end of the tubular member of the catheter stock entirely to the trailing end of the catheter stock. Independent claim 41 was amended to clarify that the coil reinforcement member is carried on the tubular member and extends from the first end thereof and terminates at eh second end thereof. Lastly, independent claim 61 was amended to clarify that the coil reinforcement member is carried on the tubular member and extends in the distal tip of the catheter completely to a second end thereof.

A further non-final Office Action was mailed from the Patent Office on January 19, 2007 wherein all pending claims were rejected. More particularly, claims 1, 3, 6-11, 24, 26-28, 41, 43, 46-53, 56-61, and 63-65 were rejected as being unpatentable over Nita. Claims 1, 3, 6-11, 24, 26-28, 41, 43, 46-53, 56-61, and 63-65 were rejected

as being unpatentable over Nita in view of Landuyt. Claims 4, 5, 44, 54, and 55 were rejected as being unpatentable over Nita in view of Follmer. Lastly, claims 4, 5, 44, 45, 54, and 55 were rejected as being unpatentable over Nita in view of Landuyt and further in view of Follmer.

Appellant filed an Amendment in response to the Office Action on April 19, 2007 in which only claim 41 was amended. More particularly, that claim was amended to clarify the recitation of a coil reinforcement member carried on the tubular member and extending from the first end thereof and which terminates at the second end thereof.

Thereafter, a Final Office Action was mailed form the Patent Office on July 2, 2007. Appellant responded by filing a Notice of Appeal on July 20, 2007.

B. Each Claim is Separately Patentable

Appellant contests the rejection of claims 1, 3-11, 24-28, and 41-65 as being unpatentable under 35 U.S.C. § 103(a) over Nita and Nita in view of Landuyt and Nita in view of Follmer, and Nita in view of Landuyt and further in view of Follmer. Each pending claim stands or falls separately. More particularly, each of claims 1, 3-11, 24-28, and 41-65 constitutes a separate group, and they stand as separately patentable claims.

C. All Pending Claims are Patentable Over Nita and Nita in view of Landuyt or Follmer

Nita:

As noted above, claims 1, 3, 6-11, 24, 26-28, 41, 43, 46-53, 56-61, and 63-65 were rejected as being unpatentable over Nita. The Examiner took the first position with regard to Nita that in column 9 at lines 9-28, Nita teaches a continuous coil reinforcement member extending from the proximal end of the catheter and terminating at the distal end thereof. Further, the Examiner took the second position that in Figure 5, the coil reinforcement member terminates at the second or distal end of the catheter and that Nita suggests that the distal nose tip section may not be present in the

embodiment shown in Figure 5 or in the other figures where a distal nose tip section has been shown. For this, the Examiner cites to column 15 at lines 7-11. Further, the Examiner took the third position that the catheter in Figure 10 is not specifically described as having a distal nose tip section and, therefore, according to the Examiner, this catheter is seen as having a continuous coil reinforcement member which extends from the proximal end of the catheter and terminates at the second or distal end thereof.

Appellant respectfully disagrees with the Examiner's interpretation of Nita and, specifically, disagrees with each of the three (3) positions set out above.

More particularly, with regard to the first and second positions, the Examiner has read column 9, lines 9-28 and column 15, lines 7-11 out of context from the rest of the specification. Essentially, it is appellant's position that Nita teaches that a bumper tip is provided in each embodiment of the catheter taught therein.

With regard to the Examiner's third position, appellants respectfully submit that the Examiner has misinterpreted the break line notations shown in Figure 10.

To fully support the above, appellant respectfully directs the attention of the Board to the Nita specification beginning at column 15, line 65 whereat it is described that:

> [w]hen we note that a coil extends to the distal end of the catheter, we intend such a statement nevertheless to include the presence of such a bumper tip (526). It is specifically noted that, however, the short distal tip (526) shown in Fig. 9 is not the same structural feature as is the comparatively lengthy most-distal section (502) in Fig. 5 which, in practice, may be 2.5 cm. or longer. Indeed, the bumper tip (526) may be used in conjunction with most-distal section (502)." (emphasis added)

Thus, according to the above, the presence of a bumper tip is specifically included in each of the embodiments of the catheters described in Nita. The bumper tip 526 is clearly shown in cross section in Figure 9 which illustrates the distal end of a catheter. As can be seen, the bumper tip 626 is free from the presence of the coil reinforcement members 522, 524. With regard to the "may be used" language set out in the citation above, appellant submits that this discussion in Nita relates to the use of bumper tip (526) of Fig. 9 with the much larger tip portion (502) of Fig. 8. Thus, when properly read in context, the bumper tip 526 "may be used" with the much larger tip

portion 502 of Figure 8 even though, as can be seen, the tip portion shown in Figure 8 is long and narrow relative to the tip portion illustrated in Figure 9.

Also, beginning at line 5 in column 15, the specification of Nita describes a small "nose" or distal tip 311 of polymer which remains distal of the distal-most extension of the coil windings. Clearly, therefore, the presence of a "nose" or a distal tip formed of a polymer is present between the terminus of the coil windings and the distal end of the catheter.

Therefore, with regard to the Examiner's first position, it is respectfully submitted that Nita does not in fact teach a continuous coil reinforcement member extending from the proximal end of the catheter and terminating at the distal end of the catheter. Rather, it teaches a coil reinforcement member extending along the body of a catheter to a terminus point near the distal end of the catheter but not at the distal end. Simply, the coil reinforcement member in Nita stops short of extending to the distal end of the catheter as specified in the citation above (col. 15, line 65-col. 16, line 6).

As to the Examiner's second position, it is respectfully submitted again that the Examiner has read some of the lines of column 15 out of context with the rest of the specification. In particular, the Examiner cites a portion of text which seemed to her to suggest the removal of the distal nose tip section from the catheter. The section cited to by the Examiner reads "[u]se of layers of coil in excess of the preferred dual layer distal-to-proximal layers is a feature independent of the presence or absence of other features, e.g., the distal nose tip section (311), shown in this figure or in others." It is respectfully submitted that the proper interpretation of this passage is that the use of layers of coil in excess of the preferred dual layer construction is a feature independent of the particular nose tip section 311 shown in Figure 5 and independent of any of the other features of the embodiments described in the Nita patent and others of equivalent construction. It is to be noted that the nose tip section 311 shown in Figure 5 is different from the bumper tip section 526 shown in Figure 8. Thus, the use of layers of coil in excess of the preferred dual layer construction is a feature independent of the particular nose tip sections 311, 526 shown in the Figures. It is to be noted, however, that both of the embodiments discussed above and as shown in Figures 5 and 8 include a coil

reinforcement member extending along the catheter but terminating at a point short of the distal end of the catheter.

Thus, the Examiner's interpretation of Nita as teaching "that the distal nose tip section may not be present in the embodiment shown in Figure 5 or in the other figures" is inaccurate and against the explicit teachings of Nita (col. 15, line 65 – col.16, line 6).

With regard to the Examiner's third position, namely that the catheter in Figure 10 is not specifically described as having a distal nose tip section and, therefore, is seen as having a continuous coil reinforcement member which extends from the proximal end of the catheter and terminates at the second or distal end thereof, appellant respectfully disagrees. The Examiner has misinterpreted the break line notations shown in Figure 10. As described in Nita at column 8, lines 32, 33, "Fig. 10 shows, in cross section, a desirable intermediate section suitable for use in the inventive catheter." Also, at column 16, beginning at line 7 it is described that "Fig. 10 depicts a variation (540) of a midsection of a highly desirable variation of this invention."

Thus, the curved lines on the left and right edges of the illustration of Figure 10 are simply break lines and do not represent either the distal or proximal ends of the catheter embodiments taught in Nita.

Landuyt:

In addition to the above, the Examiner cites Landuyt for a teaching of a desirability "to have the proximal portion of the catheter be more stiff than the distal portion" and "the use of a harder material for the second coating to achieve the desired stiffness while maintaining a softer distal portion."

Without conceding the Examiner's position with regard to Landuyt, it is respectfully submitted that neither Landuyt nor Nita as argued above teach a continuous coil reinforcement member extending from one end of the catheter to the other end.

Landuyt simply teaches an epidural catheter consisting of a length of tubing 10 having an inner layer 11 and an outer layer 12. It does not teach or suggest a catheter of the type claimed in the instant application wherein first and second layers of material are carried on a tubular member, the first layer covering a continuous coil

member extending from the first end of the catheter to the second end of the catheter and having other features as recited in the claims on appeal herein.

Follmer:

The Examiner cites to the teachings of Follmer for showing a marker band disposed adjacent the distal end of the catheter. It teaches a balloon catheter comprising a catheter body having an elastomeric balloon at a distal end. A portion of the catheter carries a stainless steel reinforcement ribbon 114 as shown in Figure 2.

However, Follmer does not teach or suggest a catheter of the type claimed in the instant application wherein first and second layers of material are carried on a tubular member, the first layer covering a continuous coil member extending from the first end of the catheter to the second end of the catheter and having other features as recited in the claims on appeal herein.

In addition, appellant respectfully submits that the Examiner needs to look no further than the teachings of Nita for a showing of a radio-opaque marker band such as shown at 108 in Figure 1, 204, 210 in Fig. 2, 236 in Fig. 3, 506, 508 in Fig. 8, and elsewhere in Nita.

It is respectfully submitted that neither Follmer nor Landuyt, nor Nita as described above teach a catheter having a continuous coil reinforcement member extending from one tip of the catheter to the other.

1. Claim 1 is Unobvious Over Nita and Nita in View of Landuyt

Independent claim 1 recites a reinforced catheter comprising an elongate flexible tubular member defining a lumen of the catheter, the tubular member having a first end defining a proximal end of the catheter and a second end defining a distal end of the catheter; a continuous coil reinforcement member carried on the elongate flexible tubular member and extending from the proximal end of the catheter and terminating at the second end of the tubular member; a first flexible outer coating covering the coil reinforcement member and the tubular member substantially entirely between the proximal end of the catheter and the distal end of the catheter; and, a second flexible outer coating covering a first portion of the first outer coating between a first transition

area of the catheter and said proximal end of the catheter, a second portion of the first outer coating between said first transition area and said distal end of the catheter being uncovered by said second outer coating and defining a flexible distal tip of said catheter, the first coating being softer than said second coating.

It is respectfully submitted that the Nita patent does not teach, suggest, or fairly disclose first and second outer coatings in a reinforced catheter wherein the second outer coating covers a portion of the first outer coating and the first coating is softer than the second coating. In addition, the Nita patent does not teach, suggest, or fairly disclose a continuous coil reinforcement member carried on an elongate flexible tubular member and extending from the proximal end of the catheter and terminating at the second end of the elongate flexible tubular member.

As to the first point above, the Examiner cites to the Nita patent at column 6, lines 11-15 which suggest that an outer layer may have a wide variety of material chosen either to enhance the lubricity of the overall catheter assembly or to provide additional stiffness to that section. However, it is to be noted that that portion of the Nita patent does not teach a second coating covering a first coating wherein the first coating is softer than the second coating. That portion of the Nita patent simply suggests that an outer coating can be used.

Also, it is respectfully submitted that the Nita patent does not teach, suggest, or fairly disclose a continuous coil reinforcement member carried on an elongate flexible tubular member and extending from the proximal end of the catheter and terminating at a second end of the tubular member. Rather, as noted above, and as specifically set out in the Nita patent at the bottom of column 15 and shown in Figure 9, a "bumper tip" portion of the catheter is provided which includes no helically wound coil portions therein. The Nita patent carefully specifies that regardless of statements in text thereof indicating that a coil extends to the distal end of the catheter, they intend such a statement nevertheless to include the presence of such a bumper tip 526 as shown in Figure 9 (column 5, l. 65). Accordingly, it is respectfully submitted that the Nita patent does not meet this limitation which is clearly set out in independent claim 1 of the present application.

In addition to the above, the Landuyt and Follmer patent do not teach or suggest a continuous coil reinforcement member terminating at a distal end of the catheter. Landuyt teaches a catheter having no coil reinforcement member at all and Follmer teaches coil reinforcement members terminating at a substantial distance from the distal end of the catheter embodiments such as shown in Figure 1.

For at least the above reasons, it is respectfully submitted that independent claim 1 is patentably distinct and unobvious over the art of record.

2. Claim 3 is Unobvious Over Nita and Nita in View of Landuyt

Claim 3 depends from claim 1 and adds the further limitations of first flexible outer coating having a Shore hardness of about 40D, and the second flexible outer coating having a Shore hardness of about 70D. It is respectfully submitted that the Examiner has not made out a prima facie case of obviousness in rejecting this claim. On page 3 of the final Office Action the Examiner suggested that the second outer coating in the embodiment shown in Figure 10 of Nita "could be chosen" to have a particular Shore hardness based on the Examiner's understanding of the description of the embodiment shown in Figure 3D and described in Nita at col. 14, lines 37-57. However, there is no teaching or suggestion in Nita that the layered structure would benefit in any way by providing layers of materials, each having a different Shore hardness as suggested by the Examiner. To the contrary, the problem of providing a stiff proximal end while having a flexible distal end is solved in the banded-type construction by providing "a third layer of ribbon (311)" (col. 15, ln. 2) with reference to the construction shown in Figure 5 or by providing an "additional exterior layer (542)" (col. 16, ln. 9) with reference to the construction shown in Figure 10. Further, Landuyt teaches only a catheter having layered materials but without any coil reinforcement members. It is respectfully submitted that the suggestion of combining the layers taught in Landuyt into the structure of Nita was derived from appellant's claims rather than from the art itself.

3. Claim 4 is Unobvious Over Nita in View of Follmer, and in view of Nita With Landuyt/Follmer

Claim 4 depends from claim 1 and adds the further limitation of the reinforced catheter comprising a marker band disposed adjacent the distal end of the catheter on the first flexible outer coating. It is respectfully submitted that Nita does not teach or suggest a catheter having a construction such as set out in claim 1 of the present application for reasons set out above. Further, neither Nita nor Landuyt teach or suggest a catheter having a construction such as set out in claim 1 and including a marker band disposed adjacent the distal end of the catheter on the first flexible outer coating thereof.

4. Claim 5 is Unobvious Over Nita in View of Follmer, and in view of Nita With Landuyt/Follmer

Claim 5 depends from claim 4 and adds the further limitation of the marker band being formed of a one of gold material and platinum material. It is respectfully submitted that Nita does not teach or suggest a catheter having a construction such as set out in claim 1 of the present application for reasons set out above. Further, neither Nita nor Landuyt teach or suggest a catheter having a construction such as set out in claim 1 and including a marker band wherein the marker band is formed of a one of gold material and platinum material.

5. Claim 6 is Unobvious Over Nita and Nita in View of Landuyt

Claim 6 depends from claim 1 and adds the further limitation of the elongate flexible tubular member being formed of a polytetrafluoroethylene (PTFE) material. It is respectfully submitted that Nita does not teach or suggest a catheter having a construction such as set out in claim 1 of the present application for reasons set out above. Further, neither Nita nor Landuyt teach or suggest a catheter having a construction such as set out in claim 1 and wherein the elongate flexible tubular member is formed of a polytetrafluoroethylene (PTFE) material.

6. Claim 7 is Unobvious Over Nita and Nita in View of Landuyt

Claim 7 depends from claim 1 and adds the further limitations of the continuous coil reinforcement member being a stainless steel wire. It is respectfully

submitted that Nita does not teach or suggest a catheter having a construction such as set out in claim 1 of the present application for reasons set out above. Further, neither Nita nor Landuyt teach or suggest a catheter having a construction such as set out in claim 1 and wherein the continuous coil reinforcement member is a stainless steel wire.

7. Claim 8 is Unobvious Over Nita and Nita in View of Landuyt

Claim 8 depends from claim 1 and adds the further limitation of the continuous coil reinforcement member defining a helical pattern. It is respectfully submitted that Nita does not teach or suggest a catheter having a construction such as set out in claim 1 of the present application for reasons set out above. Further, neither Nita nor Landuyt teach or suggest a catheter having a construction such as set out in claim 1 and wherein the continuous coil reinforcement member defines a helical pattern.

8. Claim 9 is Unobvious Over Nita and Nita in View of Landuyt

Claim 9 depends from claim 1 and adds the further limitation of a thickness of the distal end of the catheter being less than a thickness of the proximal end of the catheter. It is respectfully submitted that Nita does not teach or suggest a catheter having a construction such as set out in claim 1 of the present application for reasons set out above. Further, neither Nita nor Landuyt teach or suggest a catheter having a construction such as set out in claim 1 and wherein a thickness of the distal end of the catheter is less than a thickness of the proximal end of the catheter.

9. Claim 10 is Unobvious Over Nita and Nita in View of Landuyt

Claim 10 depends from claim 1 and adds the further limitation of the first outer coating being comprised of one of a group of materials consisting of nylon material and urethane material. It is respectfully submitted that Nita does not teach or suggest a catheter having a construction such as set out in claim 1 of the present application for reasons set out above. Further, neither Nita nor Landuyt teach or suggest a catheter having a construction such as set out in claim 1 and wherein the first outer coating is comprised of one of a group of materials consisting of nylon material and urethane material.

10. Claim 11 is Unobvious Over Nita and Nita in View of Landuyt

Claim 11 depends from claim 1 and adds the further limitation that the second outer coating is comprised of a nylon material. It is respectfully submitted that Nita does not teach or suggest a catheter having a construction such as set out in claim 1 of the present application for reasons set out above. Further, neither Nita nor Landuyt teach or suggest a catheter having a construction such as set out in claim 1 and wherein the second outer coating is comprised of a nylon material.

11. Claim 24 is Unobvious Over Nita and Nita in View of Landuyt

Independent claim 24 recites a reinforced catheter stock for manufacturing reinforced catheters, the catheter stock comprising a selected length of an elongate flexible tubular member defining a lumen of the catheter stock, the tubular member having a first end defining a lead end of the catheter stock and a second end defining a trailing end of the catheter stock; a continuous coil reinforcement member carried on the elongate flexible tubular member and extending from the lead end of the catheter stock to the trailing end of the catheter stock entirely, a continuous outer coating of a first material covering the coil reinforcement member and the tubular member substantially entirely between said lead end of the catheter stock and the trailing end of the catheter stock; and, a continuous outer coating of a second material covering said continuous outer coating of said first material substantially entirely between said lead end of the catheter stock and the trailing end of the catheter stock, said first material being softer than said second material.

Independent claim 24 recites unambiguously that the continuous coil reinforcement member element of the claimed reinforcement catheter stock is carried on the elongate flexible tubular member and extends from the lead end of the catheter stock to the trailing end of the catheter stock entirely. This language defines the structure of the recited catheter stock as including the limitation that the continuous coil reinforcement member extends up to and terminates at the trailing end of the catheter stock as well as up to and at the lead end of the catheter stock. Simply, the continuous

coil reinforcement member extends from end to end of the catheter stock. The catheter stock is for manufacturing reinforced catheters as indicated in the preamble of claim 24.

As stated in the Nita patent beginning at column 15, line 65, it is described that "[w]hen we note that a coil extends to the distal end of the catheter, we intend such a statement nevertheless to include the presence of such a bumper tip (526). Thus, catheter stock having a continuous coil reinforcement member extending from end to end thereof would not be useful in manufacturing catheters according to the Nita teachings. Such a catheter stock as recited in claim 24 is contrary to the teachings as the structure thereof includes coil reinforcement material in portions of the catheter which must be removed during manufacture. In Nita, the coil reinforcement wire is wound onto a suitable carrier or tubular substrate in a discontinuous fashion. Figures 2A-2F of Nita clearly show this. Figure 2F is a "complete catheter shaft" as noted at col. 13, ln. 55. Thus, in Nita, each catheter is individually would leaving opposite tips of the resultant catheters having portions without reinforcement coil being disposed therein.

For at least the above reasons, it is respectfully submitted that independent claim 24 is patentably distinct and unobvious over the art of record.

12. Claim 26 is Unobvious Over Nita and Nita in View of Landuyt

Claim 26 depends from claim 24 and adds the further limitations of the continuous coil reinforcement member defining a helical pattern, the first material has a Shore hardness of about 40D, and the second material having a Shore hardness of about 70D. It is respectfully submitted that the Examiner has not made out a prima facie case of obviousness in rejecting this claim. On page 3 of the final Office Action the Examiner suggested that the second outer coating in the embodiment shown in Figure 10 of Nita "could be chosen" to have a particular Shore hardness based on the Examiner's understanding of the description of the embodiment shown in Figure 3D and described in Nita at col. 14, lines 37-57. However, there is no teaching or suggestion in Nita that the layered structure would benefit in any way by providing layers of materials, each having a different Shore hardness as suggested by the Examiner. To the contrary, the problem of providing a stiff proximal end while having a flexible distal end is solved in the banded-type construction by providing "a third layer of ribbon (311)" (col.

15, ln. 2) with reference to the construction shown in Figure 5 or by providing an "additional exterior layer (542)" (col. 16, ln. 9) with reference to the construction shown in Figure 10. Further, Landuyt teaches only a catheter having layered materials but without any coil reinforcement members. It is respectfully submitted that the suggestion of combining the layers taught in Landuyt into the structure of Nita was derived from appellant's claims rather than from the art itself.

13. Claim 27 is Unobvious Over Nita and Nita in View of Landuyt

Claim 27 depends from claim 24 and adds the further limitation of the elongate flexible tubular member being a polytetrafluoroethylene (PTFE) material. It is respectfully submitted that Nita does not teach or suggest a catheter stock having a construction such as set out in claim 24 of the present application for reasons set out above. Further, neither Nita nor Landuyt teach or suggest a catheter stock having a construction such as set out in claim 24 and wherein the elongate flexible tubular member is formed of a polytetrafluoroethylene (PTFE) material.

14. Claim 28 is Unobvious Over Nita and Nita in View of Landuyt/Follmer

Claim 28 depends from claim 24 and adds the further limitation of the continuous coil reinforcement member being a stainless steel wire. It is respectfully submitted that Nita does not teach or suggest a catheter stock having a construction such as set out in claim 24 of the present application for reasons set out above. Further, neither Nita nor Landuyt teach or suggest a catheter stock having a construction such as set out in claim 24 and wherein the continuous coil reinforcement member is a stainless steel wire.

15. Claim 41 is Unobvious Over Nita and Nita in View of Landuyt

Independent claim 41 recites a reinforced catheter comprising an elongate flexible tubular member defining a lumen of the catheter, the tubular member having a first end defining a proximal end of the catheter and a second end defining a distal end of the catheter; a first flexible outer coating covering the tubular member fully between the

proximal end of the catheter to the distal end of the catheter; a second flexible outer coating covering a first portion of the first outer coating at said proximal end of the catheter, a second portion of the first outer coating being uncovered by said second outer coating at said distal end of the catheter and defining a flexible distal tip of said catheter, the first coating being softer than said second coating; and, a coil reinforcement member carried on the elongate flexible tubular member and extending from said first end of the tubular member and terminates at said second end of the tubular member.

Claim 41 includes the limitation wherein the coil reinforcement member element of the recited reinforced catheter is carried on the elongate flexible tubular member and extends from said first end of the tubular member and terminates at said second end of the tubular member.

As stated in the Nita patent at column 15, line 65, it is described that "[w]hen we note that a coil extends to the distal end of the catheter, we intend such a statement nevertheless to include the presence of such a bumper tip (526)". (emphasis added).

It is respectfully submitted that the Nita patent does not teach, suggest, or fairly disclose first and second outer coatings in a reinforced catheter wherein the second outer coating covers a portion of the first outer coating and the first coating is softer than the second coating. In addition, the Nita patent does not teach, suggest, or fairly disclose a continuous coil reinforcement member carried on an elongate flexible tubular member and extending from the proximal end of the catheter and terminating at the second end of the elongate flexible tubular member.

As to the first point above, the Examiner cites to a portion of the Nita patent which suggests that an outer layer may have a wide variety of material chosen either to enhance the lubricity of the overall catheter assembly or to provide additional stiffness to that section. However, it is to be noted that that portion of the Nita patent does not teach a second coating covering a first coating wherein the first coating is softer than the second coating. That portion of the Nita patent simply suggests that an outer coating can be used. In addition, in order to "cure" this deficiency of specific teaching of a relative softness between the first and second coatings as required in the

claim, the Examiner cites to a portion of the Nita patent which describes an embodiment of a catheter with placement of four regions of a polymeric outer coating arranged longitudinally along the length of the catheter. Clearly in independent claim 41, the second flexible outer coating is arranged radially outwardly from the first flexible outer coating rather than longitudinally along the length of the catheter as taught in Nita.

Also, it is respectfully submitted that the Nita patent does not teach, suggest, or fairly disclose a continuous coil reinforcement member carried on an elongate flexible tubular member and extending from the proximal end of the catheter and terminating at a second end of the tubular member. Rather, as noted above, and as specifically set out in the Nita patent at the bottom of column 15 and shown in Figure 9, a "bumper tip" portion of the catheter is provided which includes no helically wound coil portions therein. The appellants in the Nita patent took special care to point out that when the specification notes that a coil extends to the distal end of the catheter, they intend such a statement nevertheless to include the presence of such a bumper tip 526 as shown in Figure 9. Accordingly, it is respectfully submitted that the Nita patent does not meet this limitation which is clearly set out in independent claim 41 of the present application.

In addition to the above, the Landuyt and Follmer patents do not teach or suggest a continuous coil reinforcement member terminating at a distal end of the catheter.

For at least the above reasons, independent claim 41 is patentably distinct and unobvious over Nita and Nita in view of Landuyt or Follmer.

16. <u>Claim 43 is Unobvious Over Nita in View of Landuyt or Follmer</u>

Claim 43 depends from claim 41 and adds the further limitations of first flexible outer coating having a Shore hardness of about 40D and second flexible outer coating having a Shore hardness of about 70D. It is respectfully submitted that the Examiner has not made out a prima facie case of obviousness in rejecting this claim. On page 3 of the final Office Action the Examiner suggested that the second outer coating in the embodiment shown in Figure 10 of Nita "could be chosen" to have a particular Shore hardness based on the Examiner's understanding of the description of

the embodiment shown in Figure 3D and described in Nita at col. 14, lines 37-57. However, there is no teaching or suggestion in Nita that the layered structure would benefit in any way by providing layers of materials, each having a different Shore hardness as suggested by the Examiner. To the contrary, the problem of providing a stiff proximal end while having a flexible distal end is solved in the banded-type construction by providing "a third layer of ribbon (311)" (col. 15, ln. 2) with reference to the construction shown in Figure 5 or by providing an "additional exterior layer (542)" (col. 16, ln. 9) with reference to the construction shown in Figure 10. Further, Landuyt teaches only a catheter having layered materials but without any coil reinforcement members. It is respectfully submitted that the suggestion of combining the layers taught in Landuyt into the structure of Nita was derived from appellant's claims rather than from the art itself.

17. Claim 44 is Unobvious Over Nita in View of Follmer, and in view of Nita With Landuyt/Follmer

Claim 44 depends from claim 41 and adds the further limitation of a marker band being disposed adjacent the distal end of the catheter on the first flexible outer coating. It is respectfully submitted that Nita does not teach or suggest a catheter having a construction such as set out in claim 41 of the present application for reasons set out above. Further, neither Nita nor Landuyt teach or suggest a catheter having a construction such as set out in claim 41 and including a marker band disposed adjacent the distal end of the catheter on the first flexible outer coating thereof.

18. Claim 45 is Unobvious Over Nita in View of Follmer, and in view of Nita With Landuyt/Follmer

Claim 45 depends from claim 44 and adds the further limitation of the marker band being formed of a one of gold material and platinum material. It is respectfully submitted that Nita does not teach or suggest a catheter having a construction such as set out in claim 41 of the present application for reasons set out above. Further, neither Nita nor Landuyt teach or suggest a catheter having a

construction such as set out in claim 41 and including a marker band wherein the marker band is formed of a one of gold material and platinum material.

19. Claim 46 is Unobvious Over Nita and Nita in View of Landuyt

Claim 46 depends from claim 41 and adds the further limitation of the elongate flexible tubular member being formed of a polytetrafluoroethylene (PTFE) material. It is respectfully submitted that Nita does not teach or suggest a catheter having a construction such as set out in claim 41 of the present application for reasons set out above. Further, neither Nita nor Landuyt teach or suggest a catheter having a construction such as set out in claim 41 and wherein the elongate flexible tubular member is formed of a polytetrafluoroethylene (PTFE) material.

20. Claim 47 is Unobvious Over Nita and Nita in View of Landuyt

Claim 47 depends from claim 41 and adds the further limitation that the coil reinforcement member is a stainless steel wire. It is respectfully submitted that Nita does not teach or suggest a catheter having a construction such as set out in claim 41 of the present application for reasons set out above. Further, neither Nita nor Landuyt teach or suggest a catheter having a construction such as set out in claim 41 and wherein the continuous coil reinforcement member is a stainless steel wire.

21. Claim 48 is Unobvious Over Nita and Nita in View of Landuyt

Claim 48 depends from claim 41 and adds the further limitation that the coil reinforcement member defines a helical pattern. . It is respectfully submitted that Nita does not teach or suggest a catheter having a construction such as set out in claim 41 of the present application for reasons set out above. Further, neither Nita nor Landuyt teach or suggest a catheter having a construction such as set out in claim 41 and wherein the continuous coil reinforcement member defines a helical pattern.

22. Claim 49 is Unobvious Over Nita and Nita in View of Landuyt

Claim 49 depends from claim 41 and adds the further limitation of a thickness of the distal end of the catheter being less than a thickness of the proximal

end of the catheter. It is respectfully submitted that Nita does not teach or suggest a catheter having a construction such as set out in claim 41 of the present application for reasons set out above. Further, neither Nita nor Landuyt teach or suggest a catheter having a construction such as set out in claim 41 and wherein a thickness of the distal end of the catheter is less than a thickness of the proximal end of the catheter.

23. Claim 50 is Unobvious Over Nita and Nita in View of Landuyt

Claim 50 depends from claim 41 and adds the further limitation of the first outer coating being comprised of one of a group of materials consisting of nylon material and urethane material. It is respectfully submitted that Nita does not teach or suggest a catheter having a construction such as set out in claim 41 of the present application for reasons set out above. Further, neither Nita nor Landuyt teach or suggest a catheter having a construction such as set out in claim 41 and wherein the first outer coating is comprised of one of a group of materials consisting of nylon material and urethane material.

24. Claim 51 is Unobvious Over Nita and Nita in View of Landuyt

Claim 51 depends from claim 41 and adds the further limitation that the second outer coating being comprised of a nylon material. It is respectfully submitted that Nita does not teach or suggest a catheter having a construction such as set out in claim 41 of the present application for reasons set out above. Further, neither Nita nor Landuyt teach or suggest a catheter having a construction such as set out in claim 41 and wherein the second outer coating is comprised of a nylon material.

25. Claim 52 is Unobvious Over Nita and Nita in View of Landuyt

Independent claim 52 recites a reinforced catheter comprising an elongate flexible tubular member having first and second ends and defining a lumen of the catheter; a continuous coil reinforcement member on the elongate flexible tubular member and terminating at said first and second ends of the tubular member; a first flexible outer coating covering the coil reinforcement member and the tubular member substantially entirely between the first end and the second end of the tubular member;

and, a second flexible outer coating covering a first portion of the first outer coating from a first transition area of the catheter and terminating at said first end of tubular member, a second portion of the first outer coating being uncovered by said second outer coating and defining a flexible distal tip of said catheter from said first transition area and terminating at said second end of the tubular member, the first coating being softer than said second coating.

It is respectfully submitted that the Nita patent does not teach, suggest, or fairly disclose first and second outer coatings in a reinforced catheter wherein the second outer coating covers a portion of the first outer coating and the first coating is softer than the second coating. In addition, the Nita patent does not teach, suggest, or fairly disclose a continuous coil reinforcement member carried on an elongate flexible tubular member and extending from the proximal end of the catheter and terminating at the second end of the elongate flexible tubular member.

As to the first point above, the Examiner cites a portion of to the Nita patent which suggests that an outer layer may have a wide variety of material chosen either to enhance the lubricity of the overall catheter assembly or to provide additional stiffness to that section. However, it is to be noted that that portion of the Nita patent does not teach a second coating covering a first coating wherein the first coating is softer than the second coating. That portion of the Nita patent simply suggests that an outer coating can be used. In addition, in order to "cure" this deficiency of specific teaching of a relative softness between the first and second coatings as required in the claim, the Examiner cites to portions of the Nita patent which describe an embodiment of a catheter with placement of four regions of a polymeric outer coating arranged longitudinally along the length of the catheter. Clearly in independent claim 52, the second flexible outer coating is arranged radially outwardly from the first flexible outer coating rather than longitudinally along the length of the catheter as taught in Nita.

Also, it is respectfully submitted that the Nita patent does not teach, suggest, or fairly disclose a continuous coil reinforcement member carried on an elongate flexible tubular member and extending from the proximal end of the catheter and terminating at a second end of the tubular member. Rather, as noted above, and as specifically set out in the Nita patent at the bottom of column 15 and shown in Figure

9, a "bumper tip" portion of the catheter is provided which includes no helically wound coil portions therein. The appellants in the Nita patent took special care to point out that when the specification notes that a coil extends to the distal end of the catheter, they intend such a statement nevertheless to include the presence of such a bumper tip 526 as shown in Figure 9. Accordingly, it is respectfully submitted that the Nita patent does not meet this limitation which is clearly set out in independent claim 1 of the present application.

In addition to the above, the Landuyt and Follmer patents do not teach or suggest a continuous coil reinforcement member terminating at a distal end of the catheter.

For at least the above reasons, appellant respectfully submits that independent claim 52 is patentably distinct and unobvious over the references of record.

26. Claim 53 is Unobvious Over Nita and Nita in View of Landuyt

Claim 53 depends from claim 52 and adds the further limitations of the first flexible outer coating having a Shore hardness of about 40D and the second flexible outer coating having a Shore hardness of about 70D. It is respectfully submitted that the Examiner has not made out a prima facie case of obviousness in rejecting this claim. On page 3 of the final Office Action the Examiner suggested that the second outer coating in the embodiment shown in Figure 10 of Nita "could be chosen" to have a particular Shore hardness based on the Examiner's understanding of the description of the embodiment shown in Figure 3D and described in Nita at col. 14, lines 37-57. However, there is no teaching or suggestion in Nita that the layered structure would benefit in any way by providing layers of materials, each having a different Shore hardness as suggested by the Examiner. To the contrary, the problem of providing a stiff proximal end while having a flexible distal end is solved in the banded-type construction by providing "a third layer of ribbon (311)" (col. 15, ln. 2) with reference to the construction shown in Figure 5 or by providing an "additional exterior layer (542)" (col. 16, ln. 9) with reference to the construction shown in Figure 10. Further, Landuyt teaches only a catheter having layered materials but without any coil reinforcement members. It is respectfully submitted that the suggestion of combining the layers taught

in Landuyt into the structure of Nita was derived from appellant's claims rather than from the art itself.

27. Claim 54 is Unobvious Over Nita in View of Follmer, and in view of Nita With Landuyt/Follmer

Claim 54 depends from claim 52 and adds the further limitation of a marker band disposed adjacent the second end of the tubular member on the first flexible outer coating. It is respectfully submitted that Nita does not teach or suggest a catheter having a construction such as set out in claim 52 of the present application for reasons set out above. Further, neither Nita nor Landuyt teach or suggest a catheter having a construction such as set out in claim 52 and including a marker band disposed adjacent the distal end of the catheter on the first flexible outer coating thereof.

28. Claim 55 is Unobvious Over Nita in View of Follmer, and in view of Nita With Landuyt/Follmer

Claim 55 depends from claim 54 and adds the further limitation of the marker band being formed of a one of gold material and platinum material. It is respectfully submitted that Nita does not teach or suggest a catheter having a construction such as set out in claim 52 of the present application for reasons set out above. Further, neither Nita nor Landuyt teach or suggest a catheter having a construction such as set out in claim 52 and including a marker band wherein the marker band is formed of a one of gold material and platinum material.

29. Claim 56 is Unobvious Over Nita and Nita in View of Landuyt

Claim 56 depends from claim 52 and adds the further limitation of the elongate flexible tubular member being formed of a polytetrafluoroethylene (PTFE) material. It is respectfully submitted that Nita does not teach or suggest a catheter having a construction such as set out in claim 52 of the present application for reasons set out above. Further, neither Nita nor Landuyt teach or suggest a catheter having a construction such as set out in claim 52 and wherein the elongate flexible tubular member is formed of a polytetrafluoroethylene (PTFE) material.

30. Claim 57 is Unobvious Over Nita and Nita in View of Landuyt

Claim 57 depends from claim 52 and adds the further limitation that the continuous coil reinforcement member is a stainless steel wire. It is respectfully submitted that Nita does not teach or suggest a catheter having a construction such as set out in claim 52 of the present application for reasons set out above. Further, neither Nita nor Landuyt teach or suggest a catheter having a construction such as set out in claim 52 and wherein the continuous coil reinforcement member is a stainless steel wire.

31. Claim 58 is Unobvious Over Nita and Nita in View of Landuyt

Claim 58 depends from claim 52 and adds the further limitation that the continuous coil reinforcement member defines a helical pattern. . It is respectfully submitted that Nita does not teach or suggest a catheter having a construction such as set out in claim 52 of the present application for reasons set out above. Further, neither Nita nor Landuyt teach or suggest a catheter having a construction such as set out in claim 52 and wherein the continuous coil reinforcement member defines a helical pattern.

32. Claim 59 is Unobvious Over Nita and Nita in View of Landuyt

Claim 59 depends from claim 52 and adds the further limitation of the first outer coating being comprised of one of a group of materials consisting of nylon material and urethane material. It is respectfully submitted that Nita does not teach or suggest a catheter having a construction such as set out in claim 52 of the present application for reasons set out above. Further, neither Nita nor Landuyt teach or suggest a catheter having a construction such as set out in claim 52 and wherein the first outer coating is comprised of one of a group of materials consisting of nylon material and urethane material.

33. Claim 60 is Unobvious Over Nita and Nita in View of Landuyt

Claim 60 depends from claim 52 and adds the further limitation of the second outer coating being comprised of a nylon material. It is respectfully submitted that Nita does not teach or suggest a catheter having a construction such as set out in claim 52 of the present application for reasons set out above. Further, neither Nita nor Landuyt teach or suggest a catheter having a construction such as set out in claim 52 and wherein the second outer coating is comprised of a nylon material.

34. Claim 61 is Unobvious Over Nita and Nita in View of Landuyt

Independent claim 61 recites a reinforced catheter comprising an elongate flexible tubular member defining a lumen of the catheter, the tubular member having a first end defining a proximal end of the catheter and a second end defining a distal end of the catheter; a first flexible outer coating covering the tubular member completely from the distal end of the catheter to the proximal end of the catheter; a second flexible outer coating covering a first portion of the first outer coating at the proximal end of the catheter, a second portion of the first outer coating at the distal end of the catheter being uncovered by said second outer coating and defining a flexible distal tip of said catheter, the first coating being softer than said second coating; and, a coil reinforcement member carried on the elongate flexible tubular member and extending in said distal tip of the catheter completely to said second end.

Independent claim 61 clearly recites the extent to which the coil reinforcement member extends on the elongate flexible tubular member comprising the reinforced catheter of the claim. More particularly, the coil reinforcement member element of the recited reinforced catheter includes the limitation of the reinforcement member being carried on the elongate flexible tubular member and extending in said distal tip of the catheter completely to said second end of the elongate flexible tubular member. In addition, the reinforced catheter claimed includes first and second outer coatings, the second outer coating covering a first portion of the first outer coating and the first coating being softer than the second coating.

It is respectfully submitted that the Nita patent does not teach, suggest, or fairly disclose first and second outer coatings in a reinforced catheter wherein the second outer coating covers a portion of the first outer coating and the first coating is

softer than the second coating. In addition, the Nita patent does not teach, suggest, or fairly disclose a continuous coil reinforcement member carried on an elongate flexible tubular member and extending from the proximal end of the catheter and terminating at the second end of the elongate flexible tubular member.

Also, it is respectfully submitted that the Nita patent does not teach, suggest, or fairly disclose a continuous coil reinforcement member carried on an elongate flexible tubular member and extending from the proximal end of the catheter and terminating at a second end of the tubular member. Rather, as noted above, and as specifically set out in the Nita patent at the bottom of column 15 and shown in Figure 9, a "bumper tip" portion of the catheter is provided which includes no helically wound coil portions therein. The appellants in the Nita patent took special care to point out that when the specification notes that a coil extends to the distal end of the catheter, they intend such a statement nevertheless to include the presence of such a bumper tip 526 as shown in Figure 9. Accordingly, it is respectfully submitted that the Nita patent does not meet this limitation which is clearly set out in independent claim 61 of the present application.

In addition to the above, the Landuyt and Follmer patents do not teach or suggest a continuous coil reinforcement member terminating at a distal end of the catheter.

For at least the above reasons, it is respectfully submitted that independent claim 61 is patentably distinct and unobvious over the references of record.

35. Claim 63 is Unobvious Over Nita and Nita in View of Landuyt

Claim 63 depends from claim 61 and adds the further limitation of the coil reinforcement member terminating at said first end of said tubular member. It is respectfully submitted that Landuyt teaches no coil reinforcement members and the coil reinforcement member in Nita does not terminate at a first end of the tubular member.

36. Claim 64 is Unobvious Over Nita and Nita in View of Landuyt

Claim 64 depends from claim 63 and adds the further limitations of the first flexible outer coating having a Shore hardness of about 40D and the second flexible

outer coating having a Shore hardness of about 70D. It is respectfully submitted that the Examiner has not made out a prima facie case of obviousness in rejecting this claim. The Examiner suggested in the Office Action that the second outer coating in the embodiment shown in Figure 10 of Nita "could be chosen" to have a particular Shore hardness based on the Examiner's understanding of the description of the embodiment shown in Figure 3D and described in Nita at col. 14, lines 37-57. However, there is no teaching or suggestion in Nita that the layered structure would benefit in any way by providing layers of materials, each having a different Shore hardness as suggested by the Examiner. To the contrary, the problem of providing a stiff proximal end while having a flexible distal end is solved in the banded-type construction by providing "a third layer of ribbon (311)" (col. 15, ln. 2) with reference to the construction shown in Figure 5 or by providing an "additional exterior layer (542)" (col. 16, ln. 9) with reference to the construction shown in Figure 10. Further, Landuyt teaches only a catheter having layered materials but without any coil reinforcement members. It is respectfully submitted that the suggestion of combining the layers taught in Landuyt into the structure of Nita was derived from appellant's claims rather than from the art itself.

37. Claim 65 is Unobvious Over Nita and Nita in View of Landuyt

Independent claim 65 recites a reinforced catheter comprising an elongate flexible tubular member having first and second ends and defining a lumen of the catheter; a continuous coil reinforcement member on the elongate flexible tubular member and extending completely to and terminating at said second end of the tubular member; a first flexible outer coating covering the coil reinforcement member and the tubular member substantially entirely between the first end and the second end of the tubular member; and, a second flexible outer coating covering a first portion of the first outer coating from a first transition area of the catheter and terminating at said first end of the tubular member, a second portion of the first outer coating being uncovered by said second outer coating and defining a flexible distal tip of the catheter from said first transition area and terminating at said second end of the tubular member, the first coating being softer than said second coating.

Claim 65 clearly recites a continuous coil reinforcement member on the elongate flexible tubular member and extending completely to and terminating at said second end of the tubular member, and first and second outer coatings, the second outer coating covering a first portion of the first outer coating and the first outer coating being softer than the second outer coating.

It is respectfully submitted that the Nita patent does not teach, suggest, or fairly disclose first and second outer coatings in a reinforced catheter wherein the second outer coating covers a portion of the first outer coating and the first coating is softer than the second coating. In addition, the Nita patent does not teach, suggest, or fairly disclose a continuous coil reinforcement member carried on an elongate flexible tubular member and extending from the proximal end of the catheter and terminating at the second end of the elongate flexible tubular member.

As to the first point above, the Examiner cites to a portion of the Nita patent which suggests that an outer layer may have a wide variety of material chosen either to enhance the lubricity of the overall catheter assembly or to provide additional stiffness to that section. However, it is to be noted that that portion of the Nita patent does not teach a second coating covering a first coating wherein the first coating is softer than the second coating. That portion of the Nita patent simply suggests that an outer coating can be used. In addition, in order to "cure" this deficiency of specific teaching of a relative softness between the first and second coatings as required in the claim, the Examiner cites to a portion of the Nita patent which describes an embodiment of a catheter with placement of four regions of a polymeric outer coating arranged longitudinally along the length of the catheter. Clearly in independent claim 65, the second flexible outer coating is arranged radially outwardly from the first flexible outer coating rather than longitudinally along the length of the catheter as taught in Nita.

Also, it is respectfully submitted that the Nita patent does not teach, suggest, or fairly disclose a continuous coil reinforcement member carried on an elongate flexible tubular member and extending from the proximal end of the catheter and terminating at a second end of the tubular member. Rather, as noted above, and as specifically set out in the Nita patent at the bottom of column 15 and shown in Figure 9, a "bumper tip" portion of the catheter is provided which includes no helically wound

coil portions therein. The appellants in the Nita patent took special care to point out that when the specification notes that a coil extends to the distal end of the catheter, they intend such a statement nevertheless to include the presence of such a bumper tip 526 as shown in Figure 9. Accordingly, it is respectfully submitted that the Nita patent does not meet this limitation which is clearly set out in independent claim 1 of the present application.

In addition to the above, the Landuyt and Follmer patents do not teach or suggest a continuous coil reinforcement member terminating at a distal end of the catheter.

For at least the above reasons, appellant respectfully submits that independent claim 65 is patentably distinct and unobvious over the references of record.

CONCLUSION

For at least the above reasons, appellant respectfully submits that all pending claims are patentably distinct and unobvious over the references of record.

Allowance of all claims and early notice to that effect is respectfully requested.

Respectfully submitted,

RANKIN, HILL, PORTER & CLARK LLP

By /Michael E. Hudzinski/
Michael E. Hudzinski, Reg. No. 34,185

38210 Glenn Avenue
Willoughby, Ohio 44094-7808
(216) 566-9700

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APPENDICES

VIII. CLAIMS APPENDIX

Claims involved in the Appeal are as follows:

The status of the claims is as follows after the Amendment (of April 19, 2007) responsive to the Final Office Action of January 19, 2007:

1. (Previously Presented) A reinforced catheter comprising:

an elongate flexible tubular member defining a lumen of the catheter, the tubular member having a first end defining a proximal end of the catheter and a second end defining a distal end of the catheter;

a continuous coil reinforcement member carried on the elongate flexible tubular member and extending from the proximal end of the catheter and terminating at the second end of the tubular member;

a first flexible outer coating covering the coil reinforcement member and the tubular member substantially entirely between the proximal end of the catheter and the distal end of the catheter; and,

a second flexible outer coating covering a first portion of the first outer coating between a first transition area of the catheter and said proximal end of the catheter, a second portion of the first outer coating between said first transition area and said distal end of the catheter being uncovered by said second outer coating and defining a flexible distal tip of said catheter, the first coating being softer than said second coating.

2. (Canceled)

3. (Previously Presented) The reinforced catheter according to claim 1 wherein:

said first flexible outer coating has a Shore hardness of about 40D; and,

said second flexible outer coating has a Shore hardness of about 70D.

4. (Previously Presented) The reinforced catheter according to claim 1, further comprising a marker band disposed adjacent the distal end of the catheter on the first flexible outer coating.

5. (Original) The reinforced catheter according to claim 4, wherein the marker band is formed of a one of gold material and platinum material.

6. (Original) The reinforced catheter according to claim 1, wherein the elongate flexible tubular member is formed of a polytetrafluoroethylene (PTFE) material.

7. (Original) The reinforced catheter according to claim 1, wherein the continuous coil reinforcement member is a stainless steel wire.

8. (Original) The reinforced catheter according to claim 1, wherein the continuous coil reinforcement member defines a helical pattern.

9. (Original) The reinforced catheter according to claim 1, wherein a thickness of the distal end of the catheter is less than a thickness of the proximal end of the catheter.

10. (Original) The reinforced catheter according to claim 1, wherein the first outer coating is comprised of one of a group of materials consisting of nylon material and urethane material.

11. (Original) The reinforced catheter according to claim 1, wherein the second outer coating is comprised of a nylon material.

12. (Withdrawn) A method of manufacturing multiple reinforced catheters comprising the steps of:

providing a selected length of an elongate cylindrical tube carried on opposite first and second spool members with a portion of the cylindrical tube extending between the first and second spool members;

providing a selected length of a reinforcement wire;

for substantially the length of the cylindrical tube, advancing the cylindrical tube from the first spool member to the second spool member while simultaneously wrapping the reinforcement wire onto said portion of the cylindrical tube between the first and second spool members to form a continuous length of reinforced catheter stock;

coating the reinforced catheter stock with a predetermined thickness of a first coating and followed by a second coating harder than said first coating for substantially the length of the cylindrical tube to form a continuous length of coated catheter stock; and,

cutting the coated catheter stock at selected locations corresponding to desired catheter lengths to form a plurality of reinforced catheters.

13. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 12 further including the step of grinding the second coating of any one or more of said plurality of reinforced catheters to expose a portion of the first coating and to provide a desired outer surface finish and a desired flexibility along the longitudinal length of the catheter.

14. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 13 further including the step of swaging a marker band around the outer surface of the coating at a distal end of the any one or more of said plurality of reinforced catheters.

15. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 14, wherein the step of swaging the marker band includes swaging a marker band formed of one of a group of materials consisting of gold and platinum.

16. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 14, wherein the grinding step includes grinding a portion of the catheter beginning at a first end defining a distal end of the catheter for a predetermined distance along the longitudinal length of the catheter toward a second end defining a proximate end of the catheter.

17. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 16, wherein the grinding step includes grinding the portion of the catheter such that the thickness of the finish coating at the distal end of the catheter is less than the thickness of the finish coating at the proximate end of the catheter.

18. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 17, further including the step of coating a ground portion of the catheter with a predetermined thickness of a soft finish coating.

19. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 18, wherein the step of coating the ground portion with said soft finish coating includes coating the ground portion with a urethane material.

20. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 12, wherein the cylindrical tube is a polytetrafluoroethylene (PTFE) material.

21. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 12, wherein the reinforcement wire is a stainless steel wire.

22. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 12, wherein the wrapping step includes wrapping said reinforcement wire onto said cylindrical tube in a helical pattern.

23. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 12, wherein the coating step includes coating the reinforced catheter stock with a predetermined thickness of said first coating followed by a predetermined thickness of said second coating, the first coating having a Shore hardness of about 40D and said second coating having a Shore hardness of about 70D.

24. (Previously Presented) A reinforced catheter stock for manufacturing reinforced catheters, the catheter stock comprising:

a selected length of an elongate flexible tubular member defining a lumen of the catheter stock, the tubular member having a first end defining a lead end of the catheter stock and a second end defining a trailing end of the catheter stock;

a continuous coil reinforcement member carried on the elongate flexible tubular member and extending from the lead end of the catheter stock to the trailing end of the catheter stock entirely;

a continuous outer coating of a first material covering the coil reinforcement member and the tubular member substantially entirely between said lead end of the catheter stock and the trailing end of the catheter stock; and,

a continuous outer coating of a second material covering said continuous outer coating of said first material substantially entirely between said lead end of the catheter stock and the trailing end of the catheter stock, said first material being softer than said second material.

25. (Canceled)

26. (Previously Presented) The reinforced catheter stock according to claim 24, wherein:

the continuous coil reinforcement member defines a helical pattern;

the first material has a Shore hardness of about 40D; and,

the second material has a Shore hardness of about 70D.

27. (Original) The reinforced catheter stock according to claim 24, wherein the elongate flexible tubular member is a polytetrafluoroethylene (PTFE) material.

28. (Original) The reinforced catheter stock according to claim 24, wherein the continuous coil reinforcement member is a stainless steel wire.

29. (Withdrawn) A method of manufacturing a reinforced catheter stock, the method comprising the steps of:

providing a selected length of an elongate cylindrical tube carried on opposite first and second spool members with a portion of the cylindrical tube extending between the first and second spool members;

providing a selected length of a reinforcement wire; and

while advancing the cylindrical tube from the first spool member to the second spool member, wrapping the reinforcement wire onto the cylindrical tube at a point between the first and second spool members for substantially the length of the cylindrical tube to form a continuous length of reinforced catheter stock.

30. (Withdrawn) The method of manufacturing reinforced catheter stock according to claim 27, further comprising the step of coating the reinforced catheter stock with a predetermined thickness of a first finish coating then a second finish coating harder than said first finish coating for substantially the length of the cylindrical tube to form a continuous length of coated catheter stock.

31. (Withdrawn) The method of manufacturing reinforced catheter stock according to claim 29, wherein the step of providing said elongate cylindrical tube includes providing a polytetrafluoroethylene (PTFE) material.

32. (Withdrawn) The method of manufacturing reinforced catheter stock according to claim 29, wherein the step of providing said selected length of said reinforcement wire includes providing stainless steel wire.

33. (Withdrawn) The method of manufacturing reinforced catheter stock according to claim 29, wherein the wrapping step includes wrapping said reinforcement wire onto said cylindrical tube in a helical form.

34. (Withdrawn) An apparatus for manufacturing reinforced catheter stock, the apparatus comprising:

a first support member and a second support member, the first and second support members being spaced apart and carrying an elongate cylindrical tube with a portion of the cylindrical tube extending between the first support member and the second support member;

a winder device carrying a selected length of a reinforcement member, the winder device being adapted to wind the reinforcement member onto the cylindrical tube at a point between the first and second support members; and,

a control device simultaneously controlling i) advancement of the cylindrical tube relative to the winder device and ii) winding the reinforcement member onto said cylindrical tube by the winder device at the point between the first and second support members.

35. (Withdrawn) The apparatus according to claim 34, wherein said first support member includes a pay-out spool and said second support member includes a take-up spool, the pay-out spool and the take-up spool being responsive to the control device to pay out the elongate cylindrical tube from the pay-out spool and onto the take-up spool.

36. (Withdrawn) The apparatus according to claim 34, wherein the elongate cylindrical tube is a polytetrafluoroethylene (PTFE) material.

37. (Withdrawn) The apparatus according to claim 34, wherein the winder device includes:

a coiler tip member defining i) a central bore adapted to receive said cylindrical tube at the point between the pair of spaced apart support members, and ii) an offset opening carrying said reinforcement member, the coiler tip member being selectively rotatable relative to said cylindrical tube to wind the reinforcement member onto the cylindrical tube at selected varied angles relative to a plane perpendicular to a longitudinal axis of the cylindrical tube.

38. (Withdrawn) The apparatus according to claim 37, wherein the winder device further includes:

a motor for rotating the coiler tip member relative to the cylindrical tube;

a spool for carrying the reinforcement member; and,

a tubular member adapted to rotate with the coiler tip member to feed the reinforcement member from said spool and through the offset opening of the coiler tip member as the reinforcement member is wound onto the cylindrical tube.

39. (Withdrawn) The apparatus according to claim 38, wherein the winder device is adapted to wind the reinforcement member onto the cylindrical tube in a helical pattern.

40. (Withdrawn) The apparatus according to claim 34, wherein the reinforcement member is comprised of a stainless steel wire.

41. (Previously Presented) A reinforced catheter comprising:

an elongate flexible tubular member defining a lumen of the catheter, the tubular member having a first end defining a proximal end of the catheter and a second end defining a distal end of the catheter;

a first flexible outer coating covering the tubular member fully between the proximal end of the catheter to the distal end of the catheter;

a second flexible outer coating covering a first portion of the first outer coating at said proximal end of the catheter, a second portion of the first outer coating being uncovered by said second outer coating at said distal end of the catheter and

defining a flexible distal tip of said catheter, the first coating being softer than said second coating; and,

a coil reinforcement member carried on the elongate flexible tubular member and extending from said first end of the tubular member and terminates at said second end of the tubular member.

42. (Canceled)

43. (Previously Presented) The reinforced catheter according to claim 41 wherein:

said first flexible outer coating has a Shore hardness of about 40D; and,

said second flexible outer coating has a Shore hardness of about 70D.

44. (Previously Presented) The reinforced catheter according to claim 41, further comprising a marker band disposed adjacent the distal end of the catheter on the first flexible outer coating.

45. (Previously Presented) The reinforced catheter according to claim 44, wherein the marker band is formed of a one of gold material and platinum material.

46. (Previously Presented) The reinforced catheter according to claim 41, wherein the elongate flexible tubular member is formed of a polytetrafluoroethylene (PTFE) material.

47. (Previously Presented) The reinforced catheter according to claim 41, wherein the coil reinforcement member is a stainless steel wire.

48. (Previously Presented) The reinforced catheter according to claim 41, wherein the coil reinforcement member defines a helical pattern.

49. (Previously Presented) The reinforced catheter according to claim 41, wherein a thickness of the distal end of the catheter is less than a thickness of the proximal end of the catheter.

50. (Previously Presented) The reinforced catheter according to claim 41, wherein the first outer coating is comprised of one of a group of materials consisting of nylon material and urethane material.

51. (Previously Presented) The reinforced catheter according to claim 41, wherein the second outer coating is comprised of a nylon material.

52. (Previously Presented) A reinforced catheter comprising:

an elongate flexible tubular member having first and second ends and defining a lumen of the catheter;

a continuous coil reinforcement member on the elongate flexible tubular member and terminating at said first and second ends of the tubular member;

a first flexible outer coating covering the coil reinforcement member and the tubular member substantially entirely between the first end and the second end of the tubular member; and,

a second flexible outer coating covering a first portion of the first outer coating from a first transition area of the catheter and terminating at said first end of tubular member, a second portion of the first outer coating being uncovered by said second outer coating and defining a flexible distal tip of said catheter from said first transition area and terminating at said second end of the tubular member, the first coating being softer than said second coating.

53. (Previously Presented) The reinforced catheter according to claim 52 wherein:

said first flexible outer coating has a Shore hardness of about 40D; and,

said second flexible outer coating has a Shore hardness of about 70D.

54. (Previously Presented) The reinforced catheter according to claim 52, further comprising a marker band disposed adjacent the second end of the tubular member on the first flexible outer coating.

55. (Previously Presented) The reinforced catheter according to claim 54, wherein the marker band is formed of a one of gold material and platinum material.

56. (Previously Presented) The reinforced catheter according to claim 52, wherein the elongate flexible tubular member is formed of a polytetrafluoroethylene (PTFE) material.

57. (Previously Presented) The reinforced catheter according to claim 52, wherein the continuous coil reinforcement member is a stainless steel wire.

58. (Previously Presented) The reinforced catheter according to claim 52, wherein the continuous coil reinforcement member defines a helical pattern.

59. (Previously Presented) The reinforced catheter according to claim 52, wherein the first outer coating is comprised of one of a group of materials consisting of nylon material and urethane material.

60. (Previously Presented) The reinforced catheter according to claim 52, wherein the second outer coating is comprised of a nylon material.

61. (Previously Presented) A reinforced catheter comprising:

an elongate flexible tubular member defining a lumen of the catheter, the tubular member having a first end defining a proximal end of the catheter and a second end defining a distal end of the catheter;

a first flexible outer coating covering the tubular member completely from the distal end of the catheter to the proximal end of the catheter;

a second flexible outer coating covering a first portion of the first outer coating at the proximal end of the catheter, a second portion of the first outer coating at the distal end of the catheter being uncovered by said second outer coating and defining a flexible distal tip of said catheter, the first coating being softer than said second coating; and,

a coil reinforcement member carried on the elongate flexible tubular member and extending in said distal tip of the catheter completely to said second end.

62. (Canceled)

63. (Previously Presented) The reinforced catheter according to claim 61, wherein said coil reinforcement member terminates at said first end of said tubular member.

64. (Previously Presented) The reinforced catheter according to claim 63, wherein:

said first flexible outer coating has a Shore hardness of about 40D; and,

said second flexible outer coating has a Shore hardness of about 70D.

65. (Previously Presented) A reinforced catheter comprising:

an elongate flexible tubular member having first and second ends and defining a lumen of the catheter;

a continuous coil reinforcement member on the elongate flexible tubular member and extending completely to and terminating at said second end of the tubular member;

a first flexible outer coating covering the coil reinforcement member and the tubular member substantially entirely between the first end and the second end of the tubular member; and,

a second flexible outer coating covering a first portion of the first outer coating from a first transition area of the catheter and terminating at said first end of the tubular member, a second portion of the first outer coating being uncovered by said

second outer coating and defining a flexible distal tip of the catheter from said first transition area and terminating at said second end of the tubular member, the first coating being softer than said second coating.

IX. EVIDENCE APPENDIX

NONE

X. RELATED PROCEEDINGS APPENDIX

NONE